DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 1, 2014

Pressure Point Inc.
c/o Julie Powell,
Vice President
Quality Assurance
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K142471
Trade/Device Name: Pressure Right®, Single-Use, Disposable, Acupressure, Pressure-Sensitive Wrist Strip
Regulatory Class: Unclassified
Product Code: MVV
Dated: September 2, 2014
Received: September 3, 2014

Dear Ms. Julie Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142471

Device Name

Pressure Right®, Single-Use, Disposable, Acupressure, Pressure-Sensitive Wrist Strip (Pressure Right)

Indications for Use *(Describe)*

Pressure Right® is a drug-free, Single-Use, Pressure-Sensitive Acupressure Wrist Strip, externally applied, which is indicated for relief of nausea symptoms associated with chemotherapy, post-operative, pregnancy (morning sickness) and travel/motion.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

for

Pressure Right®, Single-Use, Disposable, Acupressure, Pressure-Sensitive Wrist

1. Submission Sponsor

Pressure Point Inc.
36 Green Meadow Drive
Tinton Falls, NJ 07724
USA
Contact: Joseph DiLustro, CEO
Phone: 1 732 747 6046

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: PHONE
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Julie Powell, VP, QA
Email: project.management@emergogroup.com

3. Date Prepared

September 2, 2014

4. Device Identification

Trade/Proprietary Name: Pressure Right®, Single-Use, Disposable, Acupressure, Pressure-Sensitive Wrist Strip (Pressure Right)

Common/Usual Name:	Pressure Band, Acupressure Device
Classification Name:	Unclassified - Device, Acupressure
Classification Regulation:	NA
Product Code:	MVV
Device Class:	U (unclassified)
Classification Panel:	Neurology

5. Legally Marketed Predicate Device(s)

Pressure Right®, Single-Use, Disposable, Acupressure, Pressure-Sensitive Wrist Strip
Manufactured by Pressure Point, Inc.
510(k) K110563

Sea-Band®
Manufactured by Sea-Band UK LTD.
510(k) K033268

6. Device Description

The Pressure Right device is a single-use, disposable acupressure strip that operates by exerting pressure on the Nei-Kuan (acupuncture) or (P6) pressure point.

The Pressure Right device has a three-quarter wrist size design (5.50" long X 1.0" wide) with an affixed hard plastic button. Its pressure stimulation effect to the P6 acupressure point provides nausea and vomiting relief for surgical patients. Pressure Right device is intended for use by adults, 18 years and older and intended to be worn on each wrist. The Pressure Right device also comes with a P6 locator template to accurately determine an individual's P6 pressure point.

7. Indication for Use Statement

Pressure Right® is a drug-free, Single-Use, Pressure-Sensitive Acupressure Wrist Strip, externally applied, which is indicated for relief of nausea symptoms associated with chemotherapy, post-operative, pregnancy (morning sickness) and travel/motion.
For Over-the-Counter (OTC) use.

8. Substantial Equivalence Discussion

The following table compares the Pressure Right OTC device to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Device Comparison Chart: Similarities and Differences

Manufacturer	**Pressure Point, Inc.**	**Pressure Point, Inc.**	**Sea-Band UK Ltd.**
Trade Name	**Pressure Right**	**Pressure Right**	**Sea-Band**
510(k) Number	**Unknown**	K110563	K033268
Product Code	MVV	MVV	MVV
Regulation Number	Unclassified	Unclassified	Unclassified
Regulation Name	Device, Acupressure	Device, Acupressure	Device, Acupressure
Indications for Use	**Pressure Right® is a drug-free, Single-Use, Pressure-Sensitive Acupressure Wrist Strip,** externally applied, which is indicated for relief of nausea symptoms associated with chemotherapy, post-operative, pregnancy (morning sickness) and travel/motion.	**Pressure Right®, Single-Use, Disposable, Pressure-Sensitive Emetic-Management Wrist Strip** is indicated for the relief of emetic (nausea and vomiting) symptoms associated with Post-Operative Anesthesia. Prescription Use	The Sea-Band Limited "Sea-Band" is indicated for the relief of nausea. Nausea is a symptom that may experienced due to a variety of causes, for example: • Travel/Motion • Pregnancy (Morning Sickness) • Chemotherapy • Post Operative

Manufacturer	Pressure Point, Inc.	Pressure Point, Inc.	Sea-Band UK Ltd.
Trade Name	**Pressure Right**	**Pressure Right**	**Sea-Band**
	Over-The-Counter Use		Over-The-Counter Use
How Supplied	Pressure Right is supplied with 2 perforated Wrist Strips in a sealed pouch with instructions for use. Pressure Right device also comes with a unique P6 locator template to aid in determining an individual's P6 pressure point.	Pressure Right is supplied with 2 perforated Wrist Strips in a sealed pouch with instructions for use. Pressure Right device also comes with a unique P6 locator template to aid in determining an individual's P6 pressure point.	Sea-Band supplied in pairs in a plastic case.
Wrist Strip Material	3M™ Transpore Surgical Tape Manufactured from a low-density perforated polyethylene film with a hypoallergenic, pressure-sensitive, acrylate adhesive.	3M™ Transpore Surgical Tape Manufactured from a low-density perforated polyethylene film with a hypoallergenic, pressure-sensitive, acrylate adhesive.	Elasticated wrist band – specific material unknown
Wrist Strip Dimension	5.50" long X 1.00" wide	5.50" long X 1.00" wide	Unknown, various sizes
Pressure Point Button Material	Acrylonitrile butadiene styrene (Lustran ABS 348), Medical Grade	Acrylonitrile butadiene styrene (Lustran ABS 348), Medical Grade	Hard Plastic
Pressure Point Button Dimension	0.52" diameter x 0.27" high	0.52" diameter x 0.27" high	0.52" diameter x 0.27" high
Typical Contact Pressure	5-7 lbs/sq. in	5-7 lbs/sq. in	5-7 lbs/sq. in
Where used	Wrist, on Nei-Kuan or (P6) acupressure point.	Wrist, on Nei-Kuan or (P6) acupressure point.	Wrist, on Nei-Kuan or (P6) acupressure point.
Device Application	Worn on both wrists, via Pressure sensitive tape / adhesive.	Worn on both wrists, via Pressure sensitive tape / adhesive	Worn on both wrist, via elastic band
Target Population	Adults, 18 years and older	Adults, 18 years and older	Adults and Children age two and up

9. Non-Clinical Performance Data

Summary of Non-Clinical Data Submitted

The following testing has been performed to support substantial equivalence:

- Bench testing to evaluate the psi pressure performance of the Pressure Right acupressure device compared to the marketed predicate (Sea-Band) device to determine pressure equivalence.

As part of demonstrating safety and effectiveness of Pressure Right device and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Pressure Point completed a number of tests. The Pressure Right device meets all the requirements for overall design, biocompatibility, and has been confirmed that the output meets the design inputs and specifications. The Pressure Right device passed the testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

There was no new clinical testing required to support the medical device as bench testing was performed to evaluate the pressure equivalence of the Pressure Right acupressure device compared to the marketed predicate (Sea-Band) device. These results were comparable and support the expanded indications of the Pressure Right device.

The predicate device, Pressure Right was clinically tested and the clinical data included in the predicate submission K110563. The predicate Pressure Right device has been on the market for several years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The Pressure Right OTC device has the same indications for use, including OTC use as the predicate Sea-Band device. The Pressure Right OTC device prescription has identical technological characteristics as the Pressure Right predicate device. The new device does not raise different questions regarding its safety and effectiveness as compared to the predicate devices.